ORBITAL AHERECTOMY IN CORONARY ARTERIES

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DISEASE STATE PREVALENCE

Coronary artery disease – large and growing problem in the US

- CHF: 5.1M
- Stroke: 6.8M
- Cancer: 13M
- CAD: 16.3M
- PAD: 18M
- Diabetes: 26M
- Kidney Disease: 31M

*Includes myocardial infarction and angina pectoris

RISKS FACTORS FOR CORONARY CALCIFICATION

Advanced Age
41.4M 65+ yrs old in U.S. ²
85+ age group is the fastest growing in the U.S.

Diabetes
Up to 26M in U.S. ¹
New epidemic, the fastest growing health problem in the U.S.

Kidney Disease
Up to 31M in U.S. ³
Diabetes is leading cause of kidney disease

Calcium Deposits in the Coronary Arteries

WHAT IS CORONARY ARTERY CALCIFICATION AND HOW DO WE DEFINE IT?

- Two definitions of coronary calcification as proposed to the ICD-10-CM/PCS Committee: angiographic or IVUS
  
  - **NONE or MILD calcification**
    - Radiopacities barely visible in close examination before contrast injection\(^1\) or IVUS reveals arc of calcium less than 90 degrees or no calcium arc\(^4\)
  
  - **MODERATE calcification**
    - Radiopacities noted only during the cardiac cycle before contrast injection\(^1,2,3\) or IVUS reveals arc of calcium 90 to 180 degrees\(^4,5\)
  
  - **SEVERE calcification**
    - Radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen\(^1,2,3\) or IVUS reveals arc of calcium greater than 180 degrees\(^4,5,6\)
  
- Incidence of severe calcification: 6%\(^7\) to 20%\(^8\)

WHY DO WE CARE ABOUT CORONARY CALCIFICATION?

- Respond poorly to angioplasty
- Difficult to completely dilate
- Prone to dissection during balloon angioplasty or predilatation
- Preclude stent delivery to the desired location
- Can prevent adequate stent expansion → restenosis, stent thrombosis, readmissions
- May result in stent malapposition
- Insufficient drug penetration and subsequent restenosis

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WHAT IS THE CURRENT STANDARD OF CARE TO TREAT CORONARY CALCIFICATION?

Balloon Angioplasty

+ 

Coronary stents
Severe calcium results in higher procedural complication rates and higher incidence of major adverse cardiac events\textsuperscript{1-3}

Patients with severely calcified coronary arteries tend to be older with higher prevalence of diabetes, kidney disease, and hypertension\textsuperscript{4-6}

Patients with Severe Calcification have worse outcomes. 1,9-12

<table>
<thead>
<tr>
<th></th>
<th>None/Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2.8%</td>
<td>1.8%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>2.8%</td>
<td>2.8%</td>
<td>4.0%</td>
</tr>
<tr>
<td>MI</td>
<td>7.3%</td>
<td>4.0%</td>
<td>9.4%</td>
</tr>
<tr>
<td>TLR</td>
<td>6.0%</td>
<td>8.2%</td>
<td>8.7%</td>
</tr>
<tr>
<td>MACE</td>
<td>7.6%</td>
<td>8.2%</td>
<td>19.9%</td>
</tr>
</tbody>
</table>

\textbf{Clinical Outcomes in Patients with Severe Calcium}


Requires more time and equipment to treat\textsuperscript{7,8}

More costly to treat\textsuperscript{7,8}

Patients with Severe Calcification have worse outcomes. 1,9-12
OTHER OPTIONS FOR TREATING CALCIFIED CORONARY ARTERIES

- Atherectomy
  - modify calcified deposits and plaques\(^1\)
  - may change artery compliance\(^2\)
  - low rate of dissections and perforations\(^3\)
  - facilitate stent delivery and expansion\(^1\)

Adequate lesion preparation with atherectomy appears to help stent implantation in severely calcified lesions.\(^4,5\)

CONVENTIONAL ATERECTOMY PROCEDURES

- **Laser**
  - Utilizes pulsed laser energy to vaporize the plaque into particles
  - Suited for removal of soft or medium plaque

- **Directional**
  - Direct and orient the cutting blade to plaque for removal
  - Does not discriminate between diseased plaque and arterial tissue
  - Suited for removal of soft or medium plaque

- **Rotational**
  - Forward drill-like mechanism
  - Rotating burr in constant contact with the lesion circumference
  - Not indicated for calcified lesions
**ROTAXUS**

240 pts with calcified lesions enrolled between August 2006 and March 2010 at 3 clinical sites in Germany

Mean age 71
DM 28%
MVD 74%

1:1 randomization

Rotablator + PES (N=120)

PTCA + PES (N=120)

IVUS not used

- 2 patients died in-hospital
- 6 patients withdrew consent
- 5 patients lost at follow-up

Clinical follow-up at 9 months in 96.2% (N=227)

Angio follow-up at 9 months in 80.5% (N=190)

*Primary endpoint: In-stent late loss

ROTAXUS: Procedural Outcomes

* Defined as <20% residual stenosis + TIMI 3 flow
** Defined as angiographic success with no crossover or stent loss
ROTAXUS PRIMARY ENDPOINT

![Graph showing 9-Month Late Lumen Loss comparing RA and PES to PTCA and PES with values 0.44 mm and 0.31 mm respectively.](image)

**ROTAXUS: 9-MONTH FOLLOW-UP**

- **Rota + PES (n=123)**

  - Death: 5.0%, P = 0.78
  - MI: 6.7%, P = 0.79
  - TVR: 16.7%, P = 0.73
  - TLR: 11.7%, P = 0.84
  - MACE*: 24.2%, P = 0.46
  - Definite ST: 0.8%, P = 1.0

- **PTCA + PES (n=132)**

  - Death: 5.8%, P = 0.78
  - MI: 5.8%, P = 0.79
  - TVR: 18.3%, P = 0.84
  - TLR: 12.5%
  - MACE*: 28.3%
  - Definite ST: 0

*Defined as death MI and TLR*
Diamondback 360° Coronary Orbital Atherectomy System (OAS)

The first and only FDA approved atherectomy device specifically indicated for severe calcium
Coronary Orbital Atherectomy utilizes an orbiting mechanism of action:

- **Differential, circumferential (orbital) sanding mechanism**
  - Differentiates between hard, calcified plaques and healthy arterial tissue

- **Variable size of lumen modification**
  - Higher speed, larger treatment area (speed controlled by the operator) – one device treat multiple vessel sizes

- **Non-occlusive**
  - Continuous flow of blood during orbit – constant cooling of minimizes thermal injury

- **Bi-directional treatment**
  - The device circumferentially sands plaque when pushed forward or pulled back
To evaluate the safety and efficacy of the coronary Orbital Atherectomy System (OAS) to prepare *de novo*, severely calcified coronary lesions for stent placement

Prospective, multi-center trial
Single arm trial *as there are no FDA-approved percutaneous treatments for patients with severely calcified lesions*

443 patients enrolled in 49 U.S. sites

30-day follow-up – published\(^1\)

1 year follow-up – published\(^2\)

2-year data – published\(^3\)

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### Patient Demographics & Lesion Characteristics

**Demographics**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>ORBIT II (N=443)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>71.4</td>
</tr>
<tr>
<td>Male</td>
<td>64.6%</td>
</tr>
<tr>
<td>History of diabetes mellitus</td>
<td>36.1%</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>91.6%</td>
</tr>
<tr>
<td>History of dyslipidemia</td>
<td>91.9%</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>14.7%</td>
</tr>
</tbody>
</table>

**Vessel & Lesion Characteristics**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe calcification</td>
<td>100%</td>
</tr>
<tr>
<td>Mean pre-procedure target lesion length</td>
<td>18.9 mm</td>
</tr>
<tr>
<td>Mean pre-procedure minimum lumen diameter</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Mean pre-procedure percent stenosis</td>
<td>84.4%</td>
</tr>
</tbody>
</table>

Real-world patients are older, more often females, with higher predicted risk of mortality, and have substantially more comorbidities such as diabetes, hypertension or dyslipidemia.1-6

5. Lind KD. AARP Public Policy Institute. 2011
**ORBIT II - Results**

### PRIMARY EFFICACY ENDPOINT
Performance goal: 82%
Procedural Success: 88.9%*

<table>
<thead>
<tr>
<th>Metric</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Stent Delivery</td>
<td>97.7%</td>
</tr>
<tr>
<td>Residual Stenosis &lt; 50%</td>
<td>98.6%</td>
</tr>
<tr>
<td>Freedom from MI (CK-MB&gt;3x ULN)</td>
<td>90.7%</td>
</tr>
<tr>
<td>- Non Q-wave</td>
<td>91.4%</td>
</tr>
<tr>
<td>- Q-wave</td>
<td>99.3%</td>
</tr>
<tr>
<td>Freedom from TVR/TLR</td>
<td>99.3%</td>
</tr>
<tr>
<td>Freedom from Cardiac Death</td>
<td>99.8%</td>
</tr>
</tbody>
</table>

### PRIMARY SAFETY ENDPOINT
Performance goal: 83%
Freedom from 30 day MACE: 89.6%

<table>
<thead>
<tr>
<th>Metric</th>
<th>Success Rate</th>
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<tbody>
<tr>
<td>Freedom from MI (CK-MB&gt;3x ULN)</td>
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<td>99.8%</td>
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*Subjects may have more than one event.*
MORTALITY

OAS has demonstrated substantial clinical improvement in reducing mortality rates in treating severely calcified lesions.


*The cited clinical trials did not involve direct device-to-device comparison and they varied in study design. The comparison shown is based upon peer-reviewed reports of the studies and is intended to show differences in classes of adverse events to support CMS need for data showing clinical improvement.
MACE Rates

OAS has demonstrated substantial clinical improvement in reducing MACE rates in treating severely calcified lesions.


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Target Lesion Revascularization Rates

OAS has demonstrated substantial clinical improvement in reducing TLR rates in treating severely calcified lesions.

<table>
<thead>
<tr>
<th>Calcification</th>
<th>9 months results</th>
<th>1 year results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORBIT II 9 mos OAS+BMS/DES</td>
<td>3.5%</td>
<td></td>
</tr>
<tr>
<td>ROTAXUS 9 mos RA+DES</td>
<td>11.7%</td>
<td>4.7%</td>
</tr>
<tr>
<td>ROTAXUS 9 mos DES alone</td>
<td>12.5%</td>
<td>8.7%</td>
</tr>
<tr>
<td>ORBIT II 1 y OAS+BMS/DES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACUITY/HORIZONS 1 y All PCI (BMS/DES)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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OAS has demonstrated that it is safe in treating de novo, severely calcified coronary lesions.
## ORBIT II 1 AND 2 YEAR TVR/TLR RATES WITHIN RANGE OF DES LITERATURE*

<table>
<thead>
<tr>
<th>ORBIT II—all stent types</th>
<th>1-year</th>
<th>2-year</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR</td>
<td>1.9%</td>
<td>2.9%</td>
</tr>
<tr>
<td>TLR</td>
<td>4.7%</td>
<td>6.2%</td>
</tr>
<tr>
<td>TVR</td>
<td>2.9%</td>
<td>5.2%</td>
</tr>
<tr>
<td>TLR</td>
<td>6.2%</td>
<td>5.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ORBIT II—DES only</th>
<th>1-year</th>
<th>2-year</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR</td>
<td>1.6%</td>
<td>2.7%</td>
</tr>
<tr>
<td>TLR</td>
<td>3.4%</td>
<td>5.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ROTAXUS—RA + DES</th>
<th>1-year</th>
<th>2-year</th>
</tr>
</thead>
<tbody>
<tr>
<td>NR</td>
<td>NR</td>
<td>19.6%</td>
</tr>
<tr>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DES RCT—severe Ca$^{2+}$ included</th>
<th>1-year</th>
<th>2-year</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR</td>
<td>0.7-7.6%$^2$</td>
<td>3.5%-11.0%$^5$</td>
</tr>
<tr>
<td>TLR</td>
<td>0.0-7.8%$^3$</td>
<td>3.7-14.9%$^4$</td>
</tr>
</tbody>
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*Literature search of coronary drug eluting stent (DES) randomized controlled trials (RCT) is on file at CSI. This summary table shows the TVR/TLR events as presented in the literature, but is not a direct device-to-device comparison since the studies described vary in design.

SUMMARY OF CLINICAL DATA

- Calcified vessels are technically challenging to treat, requiring more time and resources.

- Using the DIAMONDBACK Coronary OAS, the first and only device approved by FDA specifically to treat severely calcified lesions, offers an effective method to treat calcified coronary lesions to facilitate stent placement in these difficult-to-treat patients.

- Compared to the currently available treatments coronary orbital atherectomy has demonstrated substantial clinical improvement in treating severely calcified coronary lesions as shown by reduced rates of cardiac death, mortality, MACE, and TLR, as well as by reduced length of stay and costs.
NEED FOR CHANGES TO THE CODE STRUCTURE

- Current coding does not have a means of identifying the use of orbital atherectomy in coronary artery interventions.

- Establishing a unique qualifier will identify coronary orbital atherectomy from other currently available atherectomy treatments.

- A unique qualifier will provide the ability to collect and track:
  - Clinical data for treatment of severely calcified lesions
  - Utilization and resource costs
  - More accurate coding for reimbursement
Orbital atherectomy procedures are typically described within the Medical Record as:

- DIAMONDBACK 360®
- Orbital Atherectomy System (OAS)
- Coronary orbital atherectomy with severely calcified lesions
- Coronary orbital atherectomy with DES/BMS delivery
- Coronary orbital atherectomy with PTCA